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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,851	11/24/1999	KRIS E. HOLT	CIMA3.0-035	6771

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EXAMINER
PULLIAM, AMY E

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/449,851	Applicant(s) HOLT ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/5/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-18 and 21-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-18 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, Request for an RCE, and Amendment D, all received by the Office on August 5, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-18, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,516,524 to Kais *et al.* (hereinafter Kais). Kais teaches a pharmaceutical composition comprising doictyl sulfosuccinate (abstract). Specifically, Kais is relied upon for the teaching that double coatings are used for taste masking. Specifically, in column 11, example 6, Kais states that the objective is to eliminate the bitter taste of the drug by applying a double coating. In column 5, lines 55-60, Kais discloses that the composition can be coated with a single coating or multiple coatings, although double coating is preferred. Further, Kais teaches that the second coating can be chosen from pH sensitive polymers. Additionally, Kais states that it is preferable for the first and second coatings to be different, although the coatings can be from the same broad group of compositions, for instance both can be pH sensitive polymers. Kais further teaches Eudragit E as an example of a pH sensitive polymer which can be used in the second

coating of this invention (c 5, l 60 and c 6, l 48). Applicant does not claim any specific coatings, however, in the examples applicant uses Eudragit E as the taste masking layer. Therefore, Kais's disclosure of Eudragit E reads on applicant's claims to insolubility in saliva at neutral pH and solubility in saliva at acidic pH's as well as solubility in the stomach. Kais's coating must have these same characteristics, as these traits are inherent to the material. Kais further teaches that the coating materials can be between1 and 50 weight percent of the composition (c 8, l 10-13).

Kais does not teach the specific weight percents or thicknesses of the coatings. However, it is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations. Absent any evidence to the contrary, it is therefore the position of the examiner that the weight percents and thicknesses claimed by applicant do not change the function of the dual coating, and therefore do not merit patentable weight.

Additionally, Kais does not teach the newly added limitation that the coated drug containing core generally has a diameter of no larger than 1500 microns. However, this is because Kais does not specify the size of the coated particles. Therefore, it is entirely possible that the coated particles of Kais are the identical size to those claimed by applicant. Furthermore, the lack of detail regarding the particle size is an indication that the particle size of the Kais formulation is a manipulatable limitation, determined as part of the process of normal optimization. Lastly, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of

evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

One of ordinary skill in the art would have been motivated to make a dual coated particle with applicant's limitations, based on the teachings of Kais. One of ordinary skill in the art would expect a successful taste masked formulation regardless of specific percents and thicknesses. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed August 5, 2002 have been fully considered but are not found to be persuasive.

Applicant has amended the claims to specify that the taste masked formulation disintegrates in the mouth of the patient in less than 90 seconds to form a suspension of particles.

The examiner recognizes that applicant has amended the claims several times to include additional limitations regarding the disintegration speed of the composition in both the mouth and the stomach, as well as the size of the drug containing core. However, none of these amendments alone render patentable distinction to the instant claims. It remains the position of the examiner that Kais suggests a combination of coating layers over a drug containing core which obviates applicant's current claims. In order to overcome this obviousness rejection, the

burden is shifted to applicant to show unexpected results. More specifically, the examiner suggests that applicant supply comparative data, showing any unexpected results found in using applicant's claimed composition instead of the composition suggested by Kais. Additionally, it is recognized that Kais suggests several combinations of coating layers, one of these being a combination discussed by applicant in his specification. It is also suggested that applicant run experiments to determine if more than one of Kais' possible combinations produces the unexpected result claimed by applicant. If applicant can show that a particular combination in Kais achieves applicant's claimed result, yet another combination does not, this might overcome the current obviousness rejection. This is because Kais does not particularly state that one of his combinations is better than another, and if applicant can provide experimental data that one of the combinations does achieve superior results to the others, then the teachings of Kais do not suggest these results.

For the above reasons, this rejection is maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
October 10, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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